



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bauman et al.)
Serial No. 10/773,731) Group Art Unit: 2643
Filed: February 5, 2004) Confirmation No. 8615
For: HEARING AID SYSTEM)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

Sir:

Leon Hirsch declares and says that:

1. I am President of Vivatone Hearing Systems, LLC ("Vivatone"), and assignee of the above-referenced application. I have been intimately involved in the development, manufacture and sale of the open ear hearing aid system, which includes a behind the ear unit coupled to an open ear speaker within the ear canal since 2002.

2. The above-referenced application describes and claims an open ear hearing aid system, including a behind-the-ear amplifier and a receiver suspended within the ear canal, which receiver has an architecture that provides what I generally refer to as an "open ear configuration". More specifically, the application describes and claims, in part:

a hearing aid system, comprising:

a microphone sampling position located externally of an ear canal of a user,

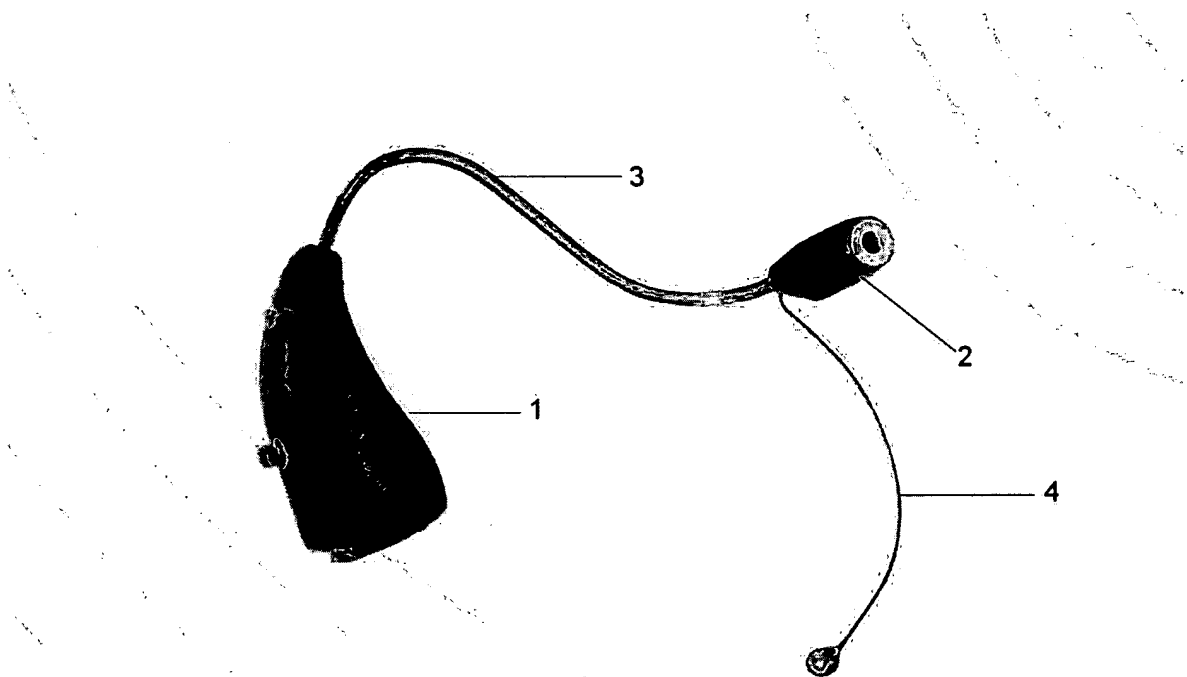
a receiver comprising a speaker positioned in an open ear configuration and suspended within said ear canal,

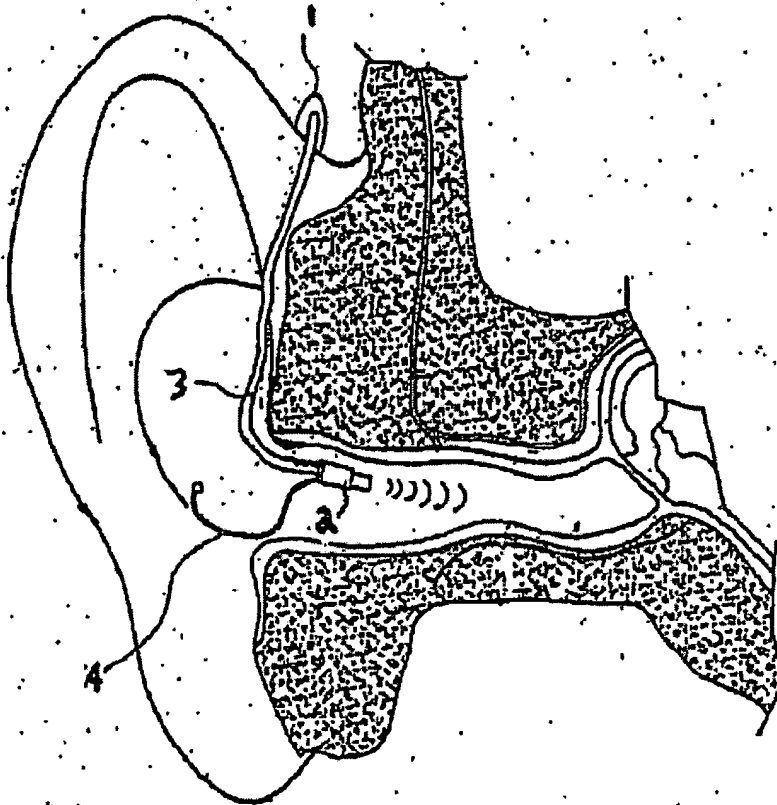
wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection

around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration, wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit.

Additionally independent claim 1 further requires that the receiver generate about three decibels or below of insertion loss over a portion of human ear audible frequencies.

3. The claims of the above-referenced claims correlate with the commercial Vivatone open ear hearing aid system. Reference is made to the following images of the commercial Vivatone device as an aid to review of the following claim chart:





The following claim chart relates aspects of the claimed Vivatone hearing aid to commercialized Vivatone hearing aid to which the above-described commercial success figures above relate. Relevant portions of independent claims (which portions are substantially reproduced in the remaining independent claims) are reproduced below:

A hearing aid, comprising: a microphone sampling position located externally of an ear canal of a user;	The Vivatone hearing aid includes a microphone and microphone port located within the behind-the-ear component (1).
a receiver comprising a speaker positioned in an open ear configuration and suspended within the ear canal;	The receiver (2) comprises a speaker (5) provided within the ear canal in an open ear configuration and is suspended within the ear canal by virtue of the stiffness of the intermediate wire (3) and/or the effect of the concha wire (4).

wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration;	The sampled sounds are passed to an amplifier provided in the behind the ear component (1), amplified in accordance with hearing loss programming and are relayed to the speaker (5) via the intermediate wire (3), which is provided around a portion of the external ear into the ear canal opening.
wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit	The microphone port and amplifier are both contained within the behind the ear component (1).

The additional aspect of the independent claim 1 is also embodied in the commercial Vivatone device, including the receiver generating about three decibels or below of insertion loss over a portion of human ear audible frequencies.

4. My open ear hearing aid was first commercially launched by Vivatone in the first quarter of 2004, and is embodied in a product designated the “Vivatone Mini”, the “Vivatone Standard” or the “Vivatone Dual”. At the time of the open ear hearing aid commercial launch, Vivatone, as a small startup company whose product line consisted solely of the open ear hearing aid product, did not have any prior reputation or name recognition. Further, there were not any significant efforts or expenditures with regard to advertising the open ear hearing aid. Indeed, Vivatone did not engage in any television or radio advertising, and only minimal other national advertising. National advertising expenses were \$1,500 in 2004 and \$16,000 in 2005, which amount is extremely minimal. Notwithstanding the lack of name recognition and advertising, Vivatone’s open ear hearing aid has achieved a high degree of commercial success. Sales were generated principally by word of mouth by audiologists, and by side-by-side demonstrations of Vivatone’s open ear hearing aid system with other hearing aids. As may be seen from the sales charts at Exhibit 1 of my September 13, 2006 Declaration, domestic unit sales and domestic net revenues have steadily increased from the first quarter of 2004 until

December 31, 2005. Domestic net revenues were \$27,000 in the first quarter of 2004, \$3,420,000 for the full year of 2004, and more than quadruple that in 2005 to \$14,500,000, including international sales. In other words, in a short two-year period, the sales of Vivatone's open ear hearing aid went from no sales to almost eighteen million dollars. Those sales came despite minimal advertising and no name recognition or prior reputation in the hearing aid field.¹

5. Various types of hearing aids have been sold marketed and sold for more than 30 years, including completely in canal (CIC) hearing aids, in-the-canal (ITC) hearing aids, in-the-ear (ITE) hearing aids and behind-the-ear (BTE) hearing aids. The first three types (CIC, ITC and ITE) occlude the ear canal by providing electronics either within the ear canal or immediately adjacent to the ear canal (e.g., in the bowl of the ear). BTE hearing aids do not occlude the ear canal, but instead provide all components in a housing behind the ear and an open tube for directing sound to the ear canal from the speaker housed in the BTE. The Vivatone open ear hearing aid is the **FIRST** product in those 30 some odd years to incorporate a design that separates the amplification from the speaker, placing the amplification behind the ear (like a BTE device, but unlike the CIC, ITC and ITE devices) while at the same time suspending a small profile speaker in the ear canal to give an open ear configuration. Thus, it took the industry 30 some odd years to create Vivatone's novel open ear hearing aid system configuration, which system minimizes insertion loss and occlusion effect and uses the ear's natural "receiver" to the fullest, mixing natural sounds and amplified sounds in the ear for excellent sound clarity (see the Vivatone Hearing System's brochure at Exhibit 2 of my September 13, 2006 Declaration).

6. While various types of hearing aids have been known for decades, no other company in the hearing aid field was motivated to separate the microphone sampling and amplification from a suspended in-canal speaker (to provide an open ear fitting remote from the BTE microphone and amplifier) until the Vivatone open ear hearing aid in 2004.

¹ However, since the introduction of the Oticon and Hansaton hearing aid products, which as discussed hereafter, constitute copies of our claimed invention, U.S. domestic sales of the Vivatone product have declined.

In my opinion, this fact alone indicates that it was not obvious to provide for such a novel open ear configuration in a hearing aid system.

7. Our open ear hearing aid system resolves the biggest problems that hearing aid wearers experienced prior to the introduction of the Vivatone hearing aid solution: occlusion, insertion loss, feedback and resonance effects (depending on the type of hearing aid used). Occlusion is the “head in the barrel” effect created when the hearing aid wearer speaks or chews. Feedback is the whistling sound experienced when a patient places a telephone near the ear or other structure. Feedback is similar to the whistling sometimes heard in an auditorium when the microphone is too close to the speaker. Further, BTE devices feeding sound to the ear canal via a sound tube suffer from resonance effects. Vivatone revolutionized hearing aids by developing a product that eliminates the *long felt need* with regard to each of these annoyances. That is, Vivatone enhances hearing while enabling the wearer to enjoy normal speaking, eating or telephone conversation without interference.

8. The reason that Vivatone hearing aids are able to provide these benefits is its unique design. Vivatone’s microphone and amplifier are housed in a small plastic case located behind the ear. Unlike other hearing aids, Vivatone delivers sound from the microphone port in the BTE electronically to its speaker in the open ear canal. The speaker is small enough to allow the ear canal to remain open, and therefore, is non-occluding. This revolutionary approach has advanced the acceptance of hearing aids significantly. As noted, prior to Vivatone, hearing aids either occluded the ear canal or transmitted sound from a speaker located behind the ear to the ear canal through a plastic tube. These designs cause either occlusion or insertion loss or distortion or lack of clarity. Vivatone’s open ear speaker allows the patient’s residual natural sound to combine with the enhanced hearing provided by Vivatone’s processor, giving crisp, clear sound to the patient.

9. I noted in my Declaration of September 13, 2006 that Oticon introduced the “Delta” hearing aid product in February, 2006 and that Hansaton announced the “Free

Soundmanager” hearing aid in March, 2006. Both of these companies are direct competitors of Vivatone. These companies copied our open ear hearing aid invention and aggressively marketed and highlighted the benefits of our open ear hearing aid invention as being a significant advance in the hearing aid field.

10. On October 17, 2006, Siemens Audiologische Technik, GmbH (“Siemens”) announced its own RIC (“Receiver in the Canal”) hearing aid, called the “CENTRA Active”, which is to be released in the beginning of 2007. *See* the Siemens press release at Exhibit 1, attached hereto. Siemens is also a direct competitor of Vivatone and is currently at least the second largest hearing aid manufacturer in the world (my understanding is that until recently, Siemens was the largest). As described below, we believe that the CENTRA Active also copies our open ear hearing aid invention; and the Siemens marketing literature related to the CENTRA Active continually and openly highlights our open ear hearing aid invention as a significant advance in the hearing aid field. More than that, Siemens is using its marketing literature in conjunction with its well known name in the hearing aid industry for its open ear CENTRA Active hearing aid.

11. Exhibit 1, Siemens’ October 17, 2006 press release, page 1, describes the CENTRA Active as “the first hearing instrument for that ‘best ager’”. The release also highlights the RIC aspect by stating, “Since the receiver is no longer within the behind-the-ear (BTE) unit, but inside the canal – and connected to the BTE via thin tubing – the BTE type is particularly small, light, and inconspicuous.” The release further states, on page 2, “This so-called receiver-in-the-canal (RIC) technology makes for particularly small and light models with pleasing cosmetics.”

12. Siemens’ CENTRA Active brochure is provided at Exhibit 2. The CENTRA Active device is described on page 1 as being “Made for active living.” The illustration includes (ignoring the tennis racket image) a BTE connected to a receiver that is suspended within the ear canal of a user. Page 3 of the brochure describes the CENTRA Active as “a new kind of Receiver-In-Canal (RIC) system.” Page 5 of the brochure

describe the aspects of the hearing aid, including the casing (A), the receiver unit (C) and the dome tip (D on the left image and E on the right image). The dome tip is described on page 6 as being an “occlusion-free dome” (used to suspend the receiver in the ear canal). The design is described as “innovative” and “discreet” on page 18. The receiver is described as being “virtually invisible.” Page 21 indicates that “CENTRA Active lets wearers live life to the fullest” and that “it is precisely the kind of innovative solution active wearers with mild to severe hearing loss are looking for.”

As is clear from the images of CENTRA Active and from the lauded language in its marketing (e.g., “innovative, discreet design”), the CENTRA Active is very similar to the Oticon Delta, the Hansaton Free Soundmanager and our Vivatone hearing aids (particularly with regard to a behind the ear unit housing an amplifier and a microphone, which is connected via an electrical wire to an open ear speaker suspended within the ear canal).

We have obviously not tested the CENTRA Active; however, review of the images of the device reveal that the device is remarkably similar to both the Oticon Delta and the Vivatone hearing aids. Accordingly, due to the apparent similarities of the Hansaton Free with the Oticon Delta and the Vivatone hearing aids, we expect that the properties of the device will be similar.

Accordingly, we expect that the CENTRA Active is embodied by independent claim 1 of the Vivatone open ear hearing aid system for which a patent was applied for more than three years prior to the announcement of the CENTRA Active and for which the Vivatone product was commercially available more than three years prior to the planned release of the CENTRA Active. We believe this to be clear evidence of copying in the industry, and as will be described below, clear evidence of laudatory remarks of our novel open ear aspects by competitors that have copied us in the marketplace.

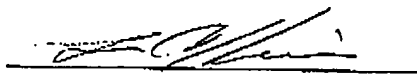
13. In addition to my belief that Siemens copied our open ear hearing aid system innovation, it is significant that the announcement and brochure of the new CENTRA Active includes laudatory statements regarding the benefits of the claimed design (that is, a BTE combined with an open ear receiver) thus supporting my contention that our open

ear hearing aid system innovation is nonobvious. I have yellow highlighted such laudatory statements in each of Exhibits 1 and 2 which state, for example:

<u>Exhibit</u>	<u>Statement</u>
1	p.1 "Since the receiver is no longer within the behind-the-ear (BTE) unit, but inside the canal – and connected to the BTE component via thin tubing – the BTE type is particularly small, light and inconspicuous." (bold)
	p.2 "This so-called receiver-in-the-canal (RIC) technology makes for particularly small and light models with pleasing cosmetics"
2	p.1 "Made for active living." (bold)
	p.3 "That's why Siemens created a new kind of Receiver-in-Canal (RIC) system." (large font)
	p.6 "occlusion free domes"
	p.18 "Innovative, discreet design"
	"Virtually invisible receiver unit"
	"Domes ... with occlusion-free fitting."
	p.21 "CENTRA Active lets wearers live life to the fullest. It is precisely the kind of innovative solution active wearers with mild to severe hearing loss are looking for."

14. As is clear from my description in Paragraphs 11-13 above, Siemens has repeatedly and continuously described our claimed hearing system as a "new" and "innovative" in the field of hearing aids. These laudatory statements exist despite the fact that various different types of hearing aids, including BTE, CIC, ITE and ITC hearing aids, have been known for decades prior to introduction of the Vivatone open ear hearing aid system.

I declare under penalty of perjury that the foregoing is true and correct.


Leon Hirsch

October 31, 2006



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EXHIBITS FOR DECLARATION UNDER 37 CFR 1.132

Sir:

Please find the attached Exhibits for the 37 C.F.R. 1.132 Declaration of Leon Hirsch, dated October 31, 2006 and filed on November 2, 2006.

EXHIBIT TABLE OF CONTENTS

The attached Exhibit includes the following:

EXHIBIT 1: Siemens Press Release Dated October 17, 2006; and

EXHIBIT 2: Siemens CENTRA Active brochure.

If there are any charges with respect to this submission or otherwise, please charge them to Deposit Account 06-1130, maintained by the Applicant's attorneys.

Respectfully submitted,

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November 2, 2006

EXHIBIT 1

Medical Solutions

Audiology Group

For the trade press

Erlangen, October 17, 2006

Siemens is showcasing the first hearing instrument for that "best ager" generation

A world's first: Moisture resistant and, when fully recharged, ready to handle even those long days

Centra Active, the latest solution in Siemens hearing instruments, is the first model specifically focused on the needs of the active older generation, a demographic segment steadily increasing worldwide. Since the receiver is no longer within the behind-the-ear (BTE) unit, but inside the canal – and connected to the BTE component via thin tubing – the BTE type is particularly small, light, and inconspicuous. Nevertheless, Centra Active offers all the breakthrough technology you have come to expect from the Centra portfolio of hearing instruments, such as "SoundSmoothing" with its attenuation of transient noise and "e2e wireless" technology. And through its unique "DataLearning" feature, the system will adapt itself to the individual preferences of its wearer. And that is not all: Centra Active is the first moisture resistant hearing instrument worldwide which, when recharged overnight, will last the entire day.

They come by many names. They are known as "best agers," "young at heart," "golden oldies," or "baby boomers." They go jogging, mountaineering or sailing, play golf and tennis, and love mountain biking. And even when it comes to their age they do not fit the mold. Sometimes they are called "50 plus" and at other times "60 plus." But it always boils down to the same thing: In the developed countries there is a burgeoning group of

active discerning consumers who are enjoying the second half of their life. And it is precisely this group of people whom Siemens had in mind when it developed its new Centra Active model.

Contrary to most conventional behind-the-ear (BTE) instruments, in the Centra Active the receiver is placed within the canal. This so-called receiver-in-the-canal (RIC) technology makes for particularly small and light models with pleasing cosmetics. Furthermore, this instrument comes not only in the standard colours of beige, granite, grey and brown, but also in black, pearl white and silver, as well as in typical hair colours.

However, its highlight is the advanced technology, especially with the moisture resistance and the cutting-edge battery technology. To date, sweat and moisture have always been regarded as the "enemies" of hearing instruments since they might interfere with their sensitive electronics. Active people, particularly those with demanding leisure activities, quite often had to put up with certain limitations. But Centra Active has relegated all that to the past because the housing is sealed by nano coating: sweat simply rolls off, while dust and dirt do not stick. In addition, the sensitive microphones are protected against moisture, rain, and splashes by an easily replaced cover. It contains a Gore membrane which is permeable to sound, but not wind and water. And the "C-Guard" membrane protects the receiver within the canal against dirt, sweat, and cerumen.

The new rechargeable battery technology is extremely user friendly. It makes changing batteries a thing of the past – just recharge the instrument overnight and it will last all day. Simply place the Centra Active into the fully automated charger. Once it is fully recharged (five hours at most) the unit will turn off automatically. Thus, the hearing instruments cannot be overcharged and will always be ready for action.

Here is a quick summary of the other technological highlights:

- "SoundSmoothing" complements present techniques for amplifying speech and attenuates transient noise exactly in those situations which often presented

problems in the past. Such examples of transient noise would be the clattering of silverware at mealtime, the clacking of high-heels on a wooden floor, or the bang of a closing door.

- "DataLearning" will let Centra Active adapt itself to the volume preferences of its wearer based on his/her personal needs and individual settings in everyday situations.
- In binaural solutions, "e2e wireless" lets two hearing instruments communicate for proper balancing at all times. This not only improves speech recognition and sound quality significantly, but directional hearing and precise position fixing of noise as well.
- Complemented by the additional advances in wind noise reduction and adaptive feedback cancellation, there are almost no applications too tough for the Centra Active to handle.

The new Centra Active will be marketed the beginning of 2007.

Siemens Medical Solutions is one of the world's largest suppliers to the healthcare industry. The company is known for bringing together innovative medical technologies, healthcare information systems, management consulting, and support services, to help customers achieve tangible, sustainable, clinical and financial outcomes. From imaging systems for diagnosis, to therapy equipment for treatment, to patient monitors to hearing instruments and beyond, Siemens innovations contribute to the health and well-being of people across the globe, while improving operational efficiencies and optimising workflow in hospitals, clinics, home health agencies, and doctors' offices. Employing approximately 33.000 people worldwide and operating in more than 120 countries, Siemens Medical Solutions reported sales of 7.6 billion EUR, orders of 8.6 billion EUR and group profit of 1 billion EUR for fiscal 2005. Further information can be found under: <http://www.siemens.com/medical>